

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 78516 UCK/TR	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)
International application No PCT/EP 03/13873	International filing date (day/month/year) 08.12.2003	Priority date (day/month/year) 08.12.2003
International Patent Classification (IPC) or both national classification and IPC INV. A61K7/16		
Applicant CADBURY SCHWEPPES PLC et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I Basis of the opinion
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 05.07.2005	Date of completion of this report 20.04.2006
Name and mailing address of the International preliminary examining authority:  European Patent Office - P B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Sierra Gonzalez, M Telephone No +31 70 340-3751

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INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

International application No. PCT/EP 03/13873

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-22 as originally filed

Claims, Numbers

1-22 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP 03/13873

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-22
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-22
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP 03/13873

Item V. Reasoned statement

1. Reference is made to the following documents:

- D1: US2003/0072841 (RAHAIAH J ET AL) 17 April 2003 (2003-04-17)
- D2: US-A-4 400 372 (KLEBER CARL J ET AL) 23 August 1983 (1983-08-23)
- D3: GB-A-2 348 370 (HODGES GERWYN TUDOR) 4 October 2000 (2000-10-04)
- D4: WO97/11675 (COLGATE-PALMOLIVE COMPANY) 3 April 1997 (1997-04-03)
(document attached)

2. INDEPENDENT CLAIM 1

- 2.1 D1 which is considered to represent the most relevant state of the art, discloses chewing gum compositions comprising more than 75% of polybutene. Thus the content of solid materials of such composition falls within the claimed ranges in claim 1 (see paragraph (0024)). The chewing gums of D1 may additionally include an abrasive. Calcium pyrophosphate is listed as possible abrasive (paragraph (0059)). The amount of 1-70% of abrasive polishing materials is suggested also in the same paragraph.
- 2.2 Thus, the specific combination of features of claim 1 has not been explicitly mentioned in D1. Accordingly, the subject-matter of claim 1 is considered to be novel over D1 and therefore it meets the criteria of Article 33(1) PCT.
- 2.3 Concerning inventive step, the problem to be solved by the present application may therefore be regarded as providing an alternative solid oral composition to whiten oral surfaces (see page 3, lines 11-21 of the description). The solution is the composition of claim 1.
- 2.4 This solution cannot however be considered as involving an inventive step for the following reasons:
- 2.5 The specific embodiment of this claim represents a mere selection of the technical features already disclosed in D1. The choice of these particular features could be arrived at by application of normal design procedures. Such a selection can only be

regarded as inventive, if it presents unexpected effects or properties in relation to the rest of the range of other possible compositions of D1. However, no such effects or properties are indicated in the application.

- 2.6 Concerning the effects or properties, the whitening effect of a composition as the one in claim 1 can not be considered unexpected. Abrasives in general and calcium pyrophosphate in particular are already known from D4 as agents active in removing stains on teeth in oral whitening compositions (D4: page 2, last paragraph; page 3, first paragraph; page 4, paragraph 3), i.e. they confer a whitening effect in some way (see also your letter dated 27.01.2006, page 6, paragraph 2).
- 2.7 The examining division agrees that whitening and abrasion are two different effects. These two effects are nevertheless associated. Abrasives are known to white the teeth to a certain extent: they help to remove extrinsic stains so that the underlying whiteness of the tooth becomes more apparent. The applicant seems also to acknowledge that abrasive agents are known to show a whitening effect (see page 1, last paragraph of the description and also your letter dated 27.01.2006, page 4, last paragraph). Therefore, it has to be concluded that an abrasive is expected to show a whitening effect.
- 2.8 No other unexpected effect or properties in relation to the other possible combinations of the broad range of D1 can be seen in the application. The fact that "the abrasive agent calcium pyrophosphate has a significantly better whitening effect compared to other commonly used abrasives" is irrelevant for the assessment of the inventive step of claim 1 (see your letter dated 27.01.2006, page 4, last paragraph and comparative examples submitted with letter dated 24.03.2006). When evaluating an inventive step it is considered important to know in what respect any new technical feature contributes to solve the problem posed and why the person skilled in the art could not arrive at the claimed subject-matter when considering the disclosure of the cited prior art (D1 in this case). The problem to be solved by the present application is not the provision of an alternative abrasive agent but the provision of an alternative whitening oral solid composition, the closest prior art being the abrasive oral solid composition of D1. In order to prove an inventive step for the present application, the applicant should have proved that the whitening effect of the composition of the application was unexpected or surprising with respect to the composition of D1 by

giving convincing arguments or by furnishing evidence (most preferable by filing test results as a comparison with the closest prior art. The applicant has failed to do that and therefore, the application has to be considered as lacking inventive step.

3. INDEPENDENT CLAIM 17

- 3.1 D1 which is considered to represent the most relevant state of the art, disclose the use of calcium pyrophosphate as abrasive material in chewing gums or confectionery compositions (D1: paragraph (0059)).
- 3.2 From this, the subject-matter of independent claim 17 differs in that the specific combination of features of claim 1 has not been disclosed for whitening the teeth. The subject-matter of claim 17 is therefore novel (Art. 33(2) PCT).
- 3.3 The problem to be solved by claim 17 may be regarded as a new use of such compositions. The solution to the problem is to use them as tooth whiteners.
- 3.4 The same reasons as explained above for claim 1 apply mutatis mutandis. As a consequence, the subject-matter of claim 17 can not be considered inventive either. Claim 17 does not fulfill the requirements of Article 33(3) PCT regarding inventive step.

4 Since the subject-matter of independent claim 20 corresponds to the subject-matter of claim 17, the same reasoning as given for claim 17 will apply mutatis mutandis.

5 DEPENDENT CLAIMS 2-16, 18-19, 21-22.

- 5.1 Dependent claims 2-16, 18-19, 21-22 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect to novelty and/or inventive step (Article 33(2) and (3) PCT).